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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/881,041
Filing Date: June 15, 2001
Appellant(s): VONK ET AL.

Stacey Longanecker, Registration Number 33, 952
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/22/2008 appealing from the Office action mailed 8/22/2007

(1) Real Party in Interest

The Real part in interest in this application and appeal is Becton Dickinson and Company by an assignment recorded September 6, 2002 on Reel 013266, Frame 0424.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,557,514	Seare et al	9-1996
5,867,821	Ballantyne et al	2-1999
5,937,387	Summerell et al	8-1999

6,283,761	Joao	9-2001
5,319,355	Russek	6-1944
2003/0055679	Soll et al	3-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al. (5,867,821 ; hereinafter Ballantyne), in view of Joao (6,283,761 ; hereinafter Joao), and in view of Summerell et al. (5,937,387; hereinafter Summerell).

(A) As per currently amended Claim 1, Ballantyne discloses a system for monitoring health-related conditions of patients, comprising:

(1) a plurality of remote monitoring stations, each being configured to receive patient health-related data pertaining to a respective patient (Ballantyne: col. 2, lines 25-26; Fig. 1-3); and

(2) a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatments that reveal population trends and outcomes, and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations and to provide a health care provider with electronic treatment

establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (Ballantyne: abstract; col. 1, line 65 - col. 2, line 63; col. 15, lines 56-65; Fig. 1-12 B).

Ballantyne, however, fails to expressly disclose a system for monitoring health-related conditions of patients, comprising:

(3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools; and

(4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient in response to said progress determination.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Summerell. In particular, Joao and Summerell disclose a system for monitoring health-related conditions of patients, comprising:

> (3) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30); and
> (4) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient in response to said progress determination (Joao: abstract; col. 4, line 26-col. 5, line 54; col. 41, line 56-col. 43, line 29; Fig. 1-15B).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne and Summerell with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

(B) As per currently amended claim 2, Ballantyne discloses a system as claimed in claim 1, wherein:

> (1) each of said remote monitoring stations comprises at least one measuring device, configured to measure a physiological condition of said respective patient, and to provide data representative of said physiological condition for inclusion among said patient health-related data (Ballantyne: col. 11, lines 18-27).

Ballantyne, however, fails to expressly disclose a system as claimed in claim 1, wherein:

> (2) said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program.

Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein

(2) said electronic assessment tools are configured to allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

(C) As per currently amended claim 3, Ballantyne discloses a system as claimed in claim 1, wherein:

said remote monitoring stations are configured to provide said patient health-related data to said computer network over the Internet (Ballantyne: Fig. 1, 5, 7B)

(D) As per previously presented claim 4, Ballantyne fails to expressly disclose a system as claimed in claim 1, wherein:

(1) said electronic assessment tools are quality of life assessment tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30) (Examiner has noted insofar as claim 4 recites "selected from the group consisting of Standard Form-36 (SF-36), Duke Activity Index, guidelines of the Diabetes Quality Improvement Project (DQIP), tools for specific

disease state monitoring, depression scales, nutrition assessment tools, quality of life assessment tools," quality of life assessment tools is recited.).

Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein:

(1) said electronic assessment tools are quality of life assessment tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

(E) As per currently amended claim 5, Ballantyne discloses a system as claimed in claim 1, wherein:

said computer network is configured to generate reports, each including health-related information pertaining to a respective said patient (Ballantyne: col. 15, lines 22-67; col. 16, lines 1-1 3).

(F) As per currently amended claim 6, Ballantyne fails to expressly disclose a system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database.

Nevertheless, these features are old and well known in the art, as evidenced by Joao. In particular, Joao discloses a system as claimed in claim 1, wherein:

said computer network is configured to provide said accumulated health-related data stored in said database to organizations financing at least a portion of said treatment programs, and is configured to receive financial data pertaining to said treatment programs from said organizations and to store said financial data in said database (Joao: col. 4, lines 31-47; col. 37, lines 35-47; Fig. 1).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned features of Joao within the Ballantyne system with the motivation of facilitating the creation, management, quality, efficiency and effectiveness of healthcare services (Joao: col. 2, lines 38-54).

(G) As per currently amended claim 7, Ballantyne discloses a system as claimed in claim 1, wherein:

each said remote monitoring station receives from its respective said patient said patient health-related data including data pertaining to the cardiovascular system of said patient (Ballantyne: col. 11, lines 18-27).

4. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne, in view of Joao, and in view of Seare et al. (5,557,514; hereinafter Seare).

(A) As per currently amended claim 8, Ballantyne fails to expressly disclose a method for monitoring health-related conditions of patients, comprising:

> (1) generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs;
> (2) receiving economic data relating to protocols used in said treatment programs;
> (3) aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care; and
> (4) determining from said aggregated data recommendations for improving the treatment programs.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Seare. In particular, Joao and Seare disclose a method for monitoring health-related conditions of patients, comprising:

(1) generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs (Joao: abstract; col. 4, line 26-col. 5, line 54; Fig. 1-15B);

(2) receiving economic data relating to protocols used in said treatment programs (Seare: abstract; Fig. 1-1 5);

(3) aggregating said patient health-related data, said clinical data and said economic data with information comprising population outcomes and generic standards of care (Seare: abstract; Fig. 1-1 5); and

(4) determining from said aggregated data recommendations for improving the treatment programs (Seare: abstract; Fig. 1-1 5).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne and Seare with the motivation of facilitating the creation, management, quality, efficiency and/ or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Seare with the combined teachings of Ballantyne and Joao with the motivation of assessing treatment programs (Seare: abstract).

The remainder of claim 8 substantially repeats the same limitations as those in claim 1 and therefore, the remainder of claim 8 is rejected for the same reasons given for claim 1 and incorporated herein.

(B) Claims 9-14 substantially repeat the same limitations as claims 2-7 and therefore, are rejected for the same reasons given for claims 2-7 and incorporated herein.

5. Claim 15-21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne, Joao, Russek (5,319,355; hereinafter Russek), and in view of Soll et al. (US 200310055679; hereinafter Soll).

(A) As per amended currently amended claim 15, Ballantyne discloses a method for managing health-related conditions of patients, comprising:

(1) collecting said healthcare data by using each said healthcare manager to collect respective patient health-related data for each respective patient in their said group of patients (Ballantyne: col. 2, lines 33-35; Fig. 11A-11 D);

(2) controlling a computer network to receive said health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each said patient in a database, said database further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes (Ballantyne: col. 12, lines 36-67 and col. 13, lines 1-1 8; Fig. 11A-11 D); and

(3) updating said accumulated data in said database based on said health-related data provided by said healthcare managers and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (Ballantyne: col. 12, lines 33-35).

Ballantyne, however, fails to expressly disclose a method for managing health-related conditions of patients, comprising:

(4) assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients;

(5) coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment plan for each respective patient in their said group of patients based on said patient health-related data pertaining to that respective patient and said accumulated data;

(6) determining whether each respective patient is suitable for participation in a treatment program;

(7) wherein the determining step comprises the steps of:

(a) obtaining agreement from a respective patient to participate in a treatment program; and

(b) receiving approval from a payer who will pay for the treatment program;

(8) wherein the controlling step comprises the steps of:

(a) receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions; and

(b) receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and

the assessment, the plan of care being used in the establishment of the treatment program for the patient.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Soll. In particular, Joao and Soll disclose a method for managing health-related conditions of patients, comprising:

(4) assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients (Russek: col. 9, lines 29-32);

(5) coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment plan for each respective patient in their said group of patients based on said patient health-related data pertaining to that respective patient and said accumulated data (Joao: col. 4, lines 33-39 and col. 12, lines 22-43);

(6) determining whether each respective patient is suitable for participation in a treatment program (Soll: abstract; ¶ [0058]; Fig. 1-27);

(7) wherein the determining step comprises the steps of:

(a) obtaining agreement from a respective patient to participate in a treatment program (Soll: abstract; ¶ [0097]; Fig. 1-27); and

(b) receiving approval from a payer who will pay for the treatment program (Joao: abstract; col. 16, lines 38-65; Fig. 1-1 5B);

(8) wherein the controlling step comprises the steps of:

(a) receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions (Joao: abstract; col. 12, lines 43-50; col. 16, lines 38-65; Fig. 1-1 5B);

(b) receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient (Soll: abstract; ¶ [0058]; Fig. 1-27).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One having ordinary skill would have found it obvious at the time of the invention to combine the teachings of Russek with the combined teachings of Ballantyne, Joao, and Soll with the motivation of providing efficient and reliable communications concerning the medical conditions of patients (Russek: col. 3, lines 28-29).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Soll with the combined teachings of Ballantyne, Joao and Russek with the motivation of providing a system and method of healthcare (Soll: ¶ [0014]).

(B) Claims 16-20 substantially repeat the same limitations as those in claims 1-7 and therefore, are rejected for the same reasons given for claims 1-7 and incorporated herein.

(C) As per previously presented claim 21, Ballantyne fails to expressly disclose a method as claimed in claim 15, wherein collecting healthcare data comprises said healthcare managers developing a client plan of care (CPOC) and a medical plan of care (MPOC), the CPOC is developed during the interview with the patient, and the MPOC is developed with at least one member of the primary care team.

Nevertheless, these features are old and well known in the art, as evidenced by Joao. In particular, Joao discloses a method as claimed in claim 15, wherein collecting healthcare data comprises said healthcare managers developing a client plan of care (CPOC) and a medical plan of care (MPOC), the CPOC is developed during the interview with the patient, and the MPOC is developed with least one member of the primary care team (Joao: col. 4, lines 40-47).
One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/ or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

(D) As per currently amended claim 23, Ballantyne discloses a method of establishing a treatment program for a patient comprising:

(1) collecting healthcare data by using said healthcare managers to collect respective patient health-related data for each of their assigned said patients (Ballantyne: col. 2, lines 33-35; Fig. 11A-11D); and

(2) controlling a computer network to receive said patient health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each of said patients in a database, said database further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes (Ballantyne: col. 12, lines 36-67 and col. 13, lines 1-1 8; Fig. 11A-11 D);

Ballantyne, however, fails to expressly disclose a method of establishing a treatment program for a patient comprising:

(3) assigning healthcare managers to patients;

(4) determining whether each of said patients is suitable for participation in a treatment program;

(5) said healthcare managers developing a respective client plan of care (CPOC) for each of their assigned said patients by interviewing them if they are selected for participation, and developing a medical plan of care (MPOC) comprising a treatment program for each of their assigned said patients in cooperation with a primary care team comprising at least one of primary care physicians, hospitals and specialists;

(6) coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking

any changes to the MPOC and updating members of the primary care team regarding the changes; and

(7) updating said accumulated data in said database based on said health-related data provided by said healthcare managers, including revisions to the CPOCs and MPOCs for respective said patients and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions.

Nevertheless, these features are old and well known in the art, as evidenced by Joao, Russek, and Soll. In particular, Joao, Russek, and Soll disclose a method of establishing a treatment program for a patient comprising:

(3) assigning healthcare managers to patients (Russek: col. 9, lines 29-32);

(4) determining whether each of said patients is suitable for participation in a treatment program (Soll: abstract; ¶ [0058]; Fig. 1-27);

(5) said healthcare managers developing a respective client plan of care (CPOC) for each of their assigned said patients by interviewing them if they are selected for participation, and developing a medical plan of care (MPOC) comprising a treatment program for each of their assigned said patients in cooperation with a primary care team comprising at least one of primary care physicians, hospitals and specialists (Joao: col. 4, lines 40-47);

(6) coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking

any changes to the MPOC and updating members of the primary care team regarding the changes (Joao: col. 4, lines 33-39; col. 7, lines 43-48; col. 12, lines 22-43); and

(7) updating said accumulated data in said database based on said health-related data provided by said healthcare managers, including revisions to the CPOCs and MPOCs for respective said patients and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions (Joao: col. 4, lines 33-39; col. 7, lines 43-48; col. 12, lines 22-43).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/ or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One having ordinary skill would have found it obvious at the time of the invention to combine the teachings of Russek with the combined teachings of Ballantyne, Joao, and Soll with the motivation of providing efficient and reliable communications concerning the medical conditions of patients (Russek: col. 3, lines 28-29).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Soll with the combined teachings of Ballantyne, Joao and Russek with the motivation of providing a system and method of healthcare (Soll: ¶ [0014]).

(E) As per currently amended claim 24, Ballantyne fails to expressly disclose a method as claimed in claim 23 further comprising:

(1) scheduling conferences between said patients and said members of the primary care team; and

(2) documenting patient-related communications comprising at least one of messages, an interview communication and conference communication during the conference and during non-scheduled patient-related communications for storage in said database.

Nevertheless, these features are old and well known in the art, as evidenced by Joao. In particular, Joao discloses a method as claimed in claim 23 further comprising:

(1) scheduling conferences between said patients and said members of the primary care team (Joao: col. 4, lines 54-55); and

(2) documenting patient-related communications comprising at least one of messages, an interview communication and conference communication during the conference and during non-scheduled patient-related communications for storage in said database (Joao: col. 16, lines 38-65).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/ or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

(F) As per previously presented claim 25, Ballantyne fails to expressly disclose a method as claimed in claim 23 further comprising:

(1) said healthcare managers following clinical encounter schedules to communicate with their said patients;
(2) using scripts to communicate with said patients during the clinical encounters; and
(3) assessing said patients' physical and psychological responses.

Nevertheless, these features are old and well known, as evidenced by Joao. In particular, Joao discloses a method as claimed in claim 23 further comprising:

(1) said healthcare managers following clinical encounter schedules to communicate with their said patients (Joao: col. 4, lines 54-55);
(2) using scripts to communicate with said patients during the clinical encounters (Joao: col. 19, lines 59-64); and
(3) assessing said patients' physical and psychological responses (Joao: col. 16, lines 38-65; Examiner also notes that Joao incorporates U.S. Pat. No. 5,961,332 by reference that teaches assessing psychological responses as well. See Joao: col. 12, lines 48-50.).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with

the motivation of facilitating the creation, management, quality, efficiency and/ or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

2. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne, Joao, Russek, in view of Soll, and in view of Official Notice.

(A) As per previously presented claim 22, Ballantyne fails to expressly disclose a method as claimed in claim 15, wherein the determining comprises excluding a respective patient based on selected criteria comprising the patient is a minor, the patient has not received a selected diagnosis, and the patient cannot communicate effectively, and including a respective patient based on selected criteria comprising having a selected primary diagnosis and being at risk for future hospital admissions.

Nevertheless, Examiner takes Official Notice of the technique of "excluding" patients from treatment programs based on various criteria such as those claimed by Applicant. For example, it is well established that minors are often excluded from certain healthcare treatment plans, such as abortions, cosmetic surgeries, and the like.

Similarly, Examiner also takes Official Notice of the technique of "including" a patient based on various criteria such as those claimed by Applicant. For example, physicians routinely subject a patient to a diagnosis and then formulate a treatment plan based on the primary diagnosis of the patient. As such, Examiner respectfully submits that the features of claim 22 are old and notoriously well known. Moreover, Examiner submits that these features were developed and widely used well prior to Applicant's claimed invention.

(10) Response to Argument

In the appeal brief filed 4/22/2008, Appellant makes the following arguments:

Within the responses below are several quotations from the Appellant. The Appellant has used the word "Applicant" to describe himself within these quotes. The Examiner has not changed Appellant's terminology.

Regarding the initial comments paragraphs, the Appellant states that, "each of these claims recites that the accumulated health-related data is revised or updated based on the patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health related conditions." The Examiner notes that this quoted statement is not found within either independent claims 1, 8 or 15. The Appellant's arguments that the references do not show this recitation are therefore considered outside this Examiner's Answer.

A. Claims 1 - 7 are NOT Obvious under 35 U.S.C. 103(a) over Ballantyne in view of Joao and further in view of Summerell.

The Appellant states that "The referenced sections of Ballantyne and the remainder of Ballantyne, however, merely refer to the storage of patient medical health records and not to the accumulated data relating to population trends and outcomes, nor revisions of this data to identify improvements of standards of care and medical practices."

- The Examiner notes that the claim states, "a database containing accumulated health-related data pertaining to health-related conditions and treatment that reveals population trends and outcomes..." The Examiner notes that, "reveals population trends and outcomes" is considered the intended use of the data and therefore has no patentable weight.
- The Examiner notes the claim continues, "said computer network being configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health related conditions."
    - Regarding claim 1, this limitation is considered the intended use of the computer network. The limitation may also be interpreted as "said computer network being configured to revise said accumulated health-related data based on said patient health-related data", as taught within Ballantyne (Figure 10B where the patient data is updated). The statement following "health-related data" and beginning with "for the identification" is then considered the intended use of the data.
    - This single limitation does not appear within claim 8. Please see additional comments below regarding claim 8.
    - The claim 15 limitation, "updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions." The Appellant admitted that Ballantyne stores patient data, above. Further, it is not clear from this claim

how the "improvements" relate to the updating of the data. These improvements could come from the usage of standardized forms to minimize errors (Ballantyne, column 15 lines 22 - 26) or the improvements may be a non-limiting mental step.

- Ballantyne references includes the ability to research the database for various needs (column 16, lines 50 - 61).

- The Appellant states that, "Summerell does not disclose an electronic self-management tool that allows a patient to integrate a health care provider's established treatment program." The Examiner notes Summerell was used for the third limitation, quoted here for convenience.

> said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools;

  - The Appellant is arguing limitations that are not claimed. There is nothing within the second limitation requiring that a health care provider be involved except to provide a treatment program.
    - Summerel column 4, lines 15 – 19, "It is yet a further object of the present invention to furnish a list of questions that the user should ask his or her doctor as he or she progresses in the personalized wellness program." The Examiner therefore believes that Summerell helps to make obvious that Appellant's invention.

- The Appellant does not argue whether Joao teaches the fourth limitation.

B. Claims 8 – 14 are NOT Obvious under 35 U.S.C. 103(a) over Ballantyne et al. and Joao in view of Seare

- The Appellant states, "For similar reasons stated above in connection with claim 1, neither Ballantyne nor Summerell singly or in combination teaches the following recitations of method claim 8 which are similar to apparatus claim 1." The Examiner disagrees for the reasons stated above. Further, the Examiner notes that Summerell is not used within the rejections of claims 8 – 14.
- Appellant states, regarding Seare and Joao, "Applicants respectfully submit that there is nothing in either of these two references that discloses or suggests revising said accumulated health-related based on said patient health-related data from remote monitoring stations, or determining from said aggregated data recommendations for improving treatment programs."
    - The Examiner includes the claim 8 limitations here:
        - obtaining patient health-related data pertaining to patients at a plurality of remote monitoring stations, each being configured to receive respective said patient health-related data from a respective said patient;
        - storing accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes in a database of a computer network;
        - receiving at said computer network said patient health-related data from said remote monitoring stations pertaining to respective patients;

- controlling said computer network to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data;
- controlling said computer network to revise said accumulated health-related data based on said patient health-related data;
- generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs;
- receiving economic data relating to protocols used in said treatment programs;
- aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care; and
- determining from said aggregated data recommendations for improving the treatment programs.

o There is nothing within the claim that describes how the data is revised. The Examiner notes that the act of storing data, in a broad interpretation, is revising that data. Further, from above, “controlling said computer network to revise said accumulated health-related data based on said patient health-related data" was rejected under Ballantyne as described within claim 1 and not Joao and not Seare as argued (Ballantyne, column 2, lines 24 - 63).

- The last limitation above, "determining from said aggregated data recommendations for improving the treatment programs," was never rejected under Joao but was rejected under Seare (Abstract) "Various treatment patterns for a particular diagnosis can be compared by treatment cost and patient outcome to determine the most cost-effective treatment approach."

- The Appellant states, "Applicants respectfully submit, for reasons stated above, that Ballantyne does not disclose a computer network for establishing treatment programs for said patients based on their respective patient health-related data and accumulated health-related data, as recited in claim 8. Seare et al. does not overcome this deficiency and therefore does not teach or suggest receiving economic data relating to protocols used in these treatment programs." The Examiner notes the piecemeal approach to the Appellant's arguments.
  - Regarding whether Ballantyne discloses, "controlling said computer network to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data," the Examiner notes the claim language. Specifically, the claim only requires that the system "provide a health care provider with electronic treatment establishment tools" and that these tools (intended use) are used to "to establish treatment programs." The claim is silent on whom or what creates the treatment programs and it is the Examiner's position that something other than the claimed method creates the treatment programs based upon said tools. Further, as the specific type of

treatment program is not claimed, any interaction between a physician and a patient could be considered part of a treatment program. (Ballantyne, column 10, lines 18 - 23 where the physician interacts with the patient and updates the PDA tool).

- The Appellant states, "In addition, Seare et al does not disclose or suggest aggregating population outcomes and generic standards of care with other data." The Examiner notes that this is not claimed.
- The Appellant states that, "Joao does not disclose generating clinical data comprising outcomes of treatment programs." The claimed language, "generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs" is similar to the Appellant's argument.
    - The Appellant's specification is silent regarding what specifically is generated except for the generation of reports (paragraphs 58 or 83 as examples). Additionally, the Appellant's specification is silent regarding what specifically is an outcome. As such, the treatment monitoring as described within Joao (column 5, lines 19 – 53) is applicable.
    - From the claim above, the generating step follows immediately after "revise said accumulated health-related data." It can be interpreted that the generating step uses the "accumulated health-related data" and not the revised "accumulated health-related data."
- The Appellant states, "If Seare et al can provide outcome information from medical provider billing data that may be arguably teach clinical data as claimed, then such

outcome data cannot be population outcome information as claimed." The Examiner is confused as the argument is not based upon claimed language and appears to be a piecemeal approach. Further, Seare, (column 21, lines 10 – 36) discusses use of 50 million historical records within the system.

- The Appellant states, "Further, since the outcomes in Figure 4 of Seare et al are only available from the raw billing data, they are not population outcomes as claimed." The Examiner is unsure what the Appellant is arguing. Seare (Abstract) states, "A method and system for analyzing historical medical provider billings to establish a normative utilization profile." The collection of individual billing records is a population outcome.

C. Claims 15 – 21 and 23 – 25 are Not Obvious under 35 U.S.C. 103(a) over Ballantyne and Joao in view of Russek and further in view of Soll et al.

- Regarding the Appellant's, "Ballantyne does not teach accumulated health-related data as recited in independent claims 15 and 23 for the reasons stated above in connection with amended claim 1", please see the comments above. Regarding the Appellant's, "Applicants respectfully submit that neither Ballantyne nor Joao teaches the updating said accumulated health-related data based on said patient health-related data, or identifying improvements in standards of care and medical practices that can be made for the different ones of the health-related conditions above in connection with the amended claim 1 or 8," please see the comments above.
- The Appellant states that, "Nothing in Soll et al discloses or suggests receiving a plan of care as a result of an interview for use in the establishment of a treatment program."

- For clarity the limitations are included here:
  - assigning healthcare managers to said patients, such that each said healthcare manager is assigned to a respective group of said patients;
  - collecting healthcare data by using each said healthcare manager to collect respective patient health-related data for each respective patient in their said group of patients;
  - determining whether each respective patient is suitable for participation in a treatment program;
  - controlling a computer network to receive said health-related data from each of said healthcare managers, and to store said patient health-related data pertaining to each said patient in a database, said database further including accumulated data pertaining to health-related conditions and treatments that reveals population trends and outcomes;
  - coordinating each said healthcare manager with at least one member of a primary care team to establish a treatment program for each respective patient in their said group of patients based on said patient health-related data pertaining to that respective patient and said accumulated data; and
  - updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions;

- wherein the determining step comprises the steps of obtaining agreement from a respective patient to participate in a treatment program; and
- receiving approval from a payer who will pay for the treatment program;
- wherein the controlling step comprises the steps of receiving health-related data for a respective patient comprising assessment of the patient's medical, psychosocial and environmental conditions;
- receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient.

  - The Examiner notes that within the claim limitations that this statement relies upon, several items are not defined.
    - For instance with "determining whether each respective patient is suitable for participation in a treatment program," nothing within this claim prevents the determination to be made during treatment or after the treatment was made as Soll, paragraph 58 describes.
    - Additionally, the step of "receiving a plan of car" does not specify that this was the initial or first plan of care. This plan may be an adjustment to an existing plan or a follow up to a previous plan as described within Soll, paragraph 58.

- The Appellant states, "Claims 16-20 are not rendered obvious for reasons stated above in connection with claims 1-7." Please see the comments above for claims 1-7.

- The Appellant states, "Regarding claims 21 and 32, the referenced section of Joao is silent regarding a CPOC and MPOC as claimed." The Examiner notes that the Appellant's specification is also silent on what exactly makes up a CPOC and a MPOC. Therefore, Joao's "healthcare and/ or healthcare-related treatment plans or programs" (column 4, line 45) is the claimed CPOC and MPOC.
    - Although the "CPOC is developed during the interview with the patient" the claim does not say whether the CPOC is completed or delivered during the interview. Also, the claimed "interview" is not defined to be only questions/ answers but may also include medical tests. Joao, column 25, line 10 through column 26, line 7 describes how the treatment plan is developed in conjunction with the examination.
    - The statement, "the MPOC is developed with at least one member of the primary care team" is dependent upon who belongs to the "primary care team." As this term in not defined, any member of the medical profession could be a participant in the primary care team.
- The Appellant states, "Claim 23 recites determining whether each respective patient is suitable for participation in a treatment program and therefore is not rendered obvious for the reasons stated above in connection with claim 15." Please see the comments above.
- Regarding claim 24, the Appellant states that "Joao lists patient data but is silent regarding documenting for storage patient-related communications during scheduled conferences and non-scheduled communications such as messages or an interview or

conference communication." The Examiner notes that the list of data stored represents non-functional descriptive information and therefore has no patentable weight.

D. Claim 22 is Not Obvious under 35 U.S.C. 103(a) over Ballantyne et al, Joao, Russek, Soll et al in view of Official Notice.

- The Appellant states, "In the Amendment filed June 8, 2007, the Applicants traversed the rejection of claim 22 based on Official Notice and requested references for at least the disclosure of excluding a patient form a treatment program based on the criteria that the patient cannot communicate effectively." Regarding a proper traversal of Official Notice, the Examiner directs the Appellant to MPEP 2144.03(c), and specifically, "To adequately traverse such a finding, an applicant must specifically point out he supposed error in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." The Examiner notes that this requirement was not done with the remarks dated June 8, 2007 and also with the appeal brief dated April 22, 2008.
- The Appellant states that the "Applicants submit that the Examiner's use of Official Notice was improper per MPEP 2144.03 since it was the principle evidence in which the rejection was based and not was employed merely to fill the gaps." The Examiner notes that claim 22 is dependent upon independent claim 15. The Official notice is used to fill in the gap of this dependent claim.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/N. R. S./

Examiner, Art Unit 3626

Conferees:

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626

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